SEP 21 2001

K012814

510 (k) Summary of Safety And Effectiveness

Applicant name and address:	Collagen Matrix, Inc. 509 Commerce Street Franklin Lakes, NJ 07417
Contact person and telephone number:	Shu-Tung Li, Ph.D. President & CEO Tel: (201) 405-1477
Date of summary:	August 20, 2001
Device generic name:	Collagen Nerve Cuff
Device trade name:	None
Substantial Equivalence:	NeuroGen™ Nerve Guide [510(k) #K011168] SaluMedica™ Nerve Cuff [510(k) #K002098] Fastube™ Nerve Cuff [510(k) #K850785]

Description of the device:

The Collagen Nerve Cuff is designed to be a flexible, resorbable and semipermeable tubular membrane matrix to provide a protective environment for peripheral nerve repair after injury and to create a conduit for axonal growth across a nerve gap.

Intended Use of the Device

The Collagen Nerve Cuff is intended for use in repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Technical Characteristics

The Collagen Nerve Cuff is designed for the repair of peripheral nerves. Specifically, the device is designed to be resorbable, flexible, suturable, biocompatible, cell occlusive, and clinically manageable.

Summary of Biocompatibility Studies

The Collagen Nerve Cuff is biocompatible based on the test recommended by the FDA and meets the ISO 10993 requirements for biocompatibility testing.

Performance Characteristics

a. Animal Data

The animal studies over the past twenty years using nerve conduit have been reviewed and have demonstrated the efficacy of peripheral nerve repair using resorbable and non-resorbable biocompatible nerve conduits .

b. Summary of Clinical Data

The results reported in the literature demonstrated efficacy of peripheral nerve repair using resorbable and non-resorbable biocompatible nerve conduits.

c. Simulated Clinical Environment

The mechanical and physical characteristics of the Collagen Nerve Cuff were evaluated in simulated clinical environment studies. The results of the studies demonstrated that the Collagen Nerve Cuff has adequate mechanical and physical characteristics for peripheral nerve repair.

Conclusion

The results of biocompatibility testing, summary of published results of animal and human studies from the literature research, simulated clinical studies, and the comparison of Collagen Nerve Cuff with other predicate devices, we conclude the following.

1. The Collagen Nerve Cuff is safe for implantation as demonstrated by the biocompatibility studies.

2. The Collagen Nerve Cuff is effective for bridging nerve gaps and guiding the axonal growth in peripheral nerve repair procedure under the proposed conditions of use.
3. The Collagen Nerve Cuff is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

Dr. Shu-Tung Li
President and CEO
Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K012814
Trade/Device Name: Collagen Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: August 21, 2001
Received: August 22, 2001

Dear Dr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walter, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.
f/t:HFZ-410:MAdjodha:dlw:09-18-01

510(k) Number (if known): K012814

Device Name: Collagen Nerve Cuff

Indications for Use:

Collagen Nerve Cuff is intended for use in repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012814